

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively the “United States”) and the State of Illinois, acting through the Illinois Attorney General and on behalf of the Illinois Department of Health and Family Services (“the State”), and Teva Pharmaceuticals USA, Inc. and IVAX LLC (formerly known as IVAX Corporation) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware company that is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., a pharmaceutical company headquartered in Israel. Teva USA manufactures and distributes generic pharmaceuticals, including Clozapine. IVAX Corporation (“IVAX”) was a Florida company that manufactured and distributed generic pharmaceuticals, including Clozapine. IVAX became an indirect wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. on January 26, 2006 and on October 29, 2009 converted to IVAX LLC, a Florida limited liability company. As used hereafter, “Teva” refers to both Teva USA and IVAX LLC.

B. Michael J. Reinstein, M.D. is a psychiatrist practicing in Chicago, Illinois and the surrounding communities.

C. The United States and the State of Illinois contend that IVAX and Teva USA caused to be submitted claims for payment to the Medicare Program (Medicare), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and the Illinois Medicaid Program (Medicaid), Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1397w-5.

D. The United States and the State of Illinois contend that they have certain civil claims against Teva USA and IVAX arising from payments by IVAX and Teva USA to Dr. Michael J. Reinstein in exchange for Reinstein prescribing Clozapine to Medicare and Medicaid patients during the period from August 20, 2003 through November 30, 2009 in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. The United States and the State of Illinois contend that during that same period, Ivax and Teva USA caused the submission of false claims to the Medicare and Medicaid programs for Clozapine prescribed by Dr. Reinstein to his Medicare and Medicaid patients, in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733 and the Illinois False Claims Act, 740 ILCS 175/3. That conduct is referred to below as the Covered Conduct.

E. This Settlement Agreement is neither an admission of liability by Teva nor a concession by the United States or the State of Illinois that their claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Teva agrees to pay the total amount of twenty-seven million, six hundred eighty-one thousand, six hundred ninety eight dollars (\$27,681,698) (“Settlement Amount”) and interest on the Settlement Amount at a rate of 2.375% from September 26, 2013 to the date of payment. The payment shall be made as follows:

(a) Teva shall pay to the United States \$15,495,347 (plus accrued interest) by electronic funds transfer pursuant to written instructions to be provided by the Office of the

United States Attorney for the Northern District of Illinois no later than ten days after the Effective Date of this Agreement.

(b) Teva shall pay the State of Illinois \$12,186,351 (plus accrued interest) by electronic funds transfer pursuant to written instructions to be provided by the Office of the Illinois Attorney General no later than ten days after the Effective Date of this Agreement.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, in consideration of Teva's obligations under this agreement, and conditioned upon Teva's full payment of the Settlement Amount, the United States releases Teva together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; and the successors and assigns of any of them from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision creating a cause of action for civil damages or civil penalties that the Civil Division of the Department of Justice has actual and present authority to assert or compromise pursuant to 28 C.F.R. Part O, Subpart I, 28 C.F.R. § 0.45(d); or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. Subject to the exceptions in paragraph 5 below, in consideration of the obligations of Teva set forth in this Agreement and conditioned upon Teva's full payment of the Settlement Amount, the Illinois Department of Health and Family Services ("HFS") and the State of Illinois agree to release Teva together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former owners; and the successors and assigns of any of them, from any civil or administrative monetary claim HFS or

the State of Illinois has or may have under the Illinois False Claims Act, 740 ILCS 175/3, and the Civil Remedies Section of the Public Aid Act, 89 Ill. Adm. Code 140.16, 305 ILCS 5/8A-7 and 305 ILCS 5/12-4.25(A) or the common law theories of payment by mistake, unjust enrichment, breach of contract and fraud, for the Covered Conduct. Nothing in this paragraph precludes HFS or the State of Illinois from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in paragraph 5.

4. Notwithstanding the release given in paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including permissive or mandatory exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for failure to deliver goods or services due;
- h. Any liability of individuals (including current or former directors, officers, employees, agents, or shareholders of IVAX or Teva) who receive written notification that they are the target of a criminal investigation (as defined in the United States Attorneys' Manual), are indicted or charged, or who enter into a plea agreement, related to the Covered Conduct.

5. Notwithstanding any term of this Agreement, the State of Illinois specifically does not release any person or entity from any of the following liabilities:

- a. Any criminal, civil, or administrative claims arising under state revenue codes;
- b. Any criminal liability;
- c. Any civil liability under any state statute, regulation, or rule not expressly covered by this Agreement, including, but not limited to any civil liability for state antitrust violations; any liability for claims involving unfair and/or deceptive acts and practices; any liability under the State's consumer protection laws which any person or entity has or may have to individual consumers or state program payors other than the Medicaid Program;
- d. Any liability to the State (or any agencies thereof) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from the State's Medicaid program;
- g. Any express or implied warranty claims or other claims for defective or deficient products and services provided by IVAX or Teva;
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
- i. Any liability based on a failure to deliver items or services due;
- j. Any liability which may be asserted by private payors or insurers, including those that are paid by a state's Medicaid program on a capitated basis; or

- k. Any liability related to the improper inflation of Average Wholesale Prices and Wholesale Acquisition costs.

6. Teva waives and shall not assert any defenses Teva may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States or the State of Illinois concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code and/or Chapter 35 or Chapter 320 of the Illinois Compiled Statutes.

7. Teva fully and finally releases the United States and the State of Illinois, their agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Teva has asserted, could have asserted, or may assert in the future against the United States or the State of Illinois, and their agencies, employees, servants, and agents, related to the Covered Conduct and the United States' and the State of Illinois' investigation and prosecution thereof.

8. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any State payer, related to the Covered Conduct; and Teva agrees not to resubmit or cause others to resubmit to any Medicare contractor or any State payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

9. Teva agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Teva, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Teva's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Teva makes to the United States pursuant to this Agreement.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Teva, and Teva shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Teva or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or Federal Employees Health Benefits Program (FEHBP) Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Teva further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable

Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Teva or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Teva agrees that the United States, at a minimum, shall be entitled to recoup from Teva any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Teva or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Teva or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the right of the United States to audit, examine, or re-examine Teva's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

10. Teva agrees to cooperate fully and truthfully with the United States' and the State of Illinois' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Teva shall encourage, and agrees not to impair, the cooperation of its

directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Teva further agrees to furnish to the United States and the State of Illinois, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf. Nothing in this Paragraph shall be construed as a waiver of any applicable privilege by Teva or an agreement to waive any such privilege.

11. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 12 (waiver for beneficiaries paragraph), below.

12. Teva agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

13. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

14. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

15. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Northern District of Illinois. For purposes of construing this Agreement, this

Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

16. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

17. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

18. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

19. This Agreement is binding on Teva's successors, transferees, heirs, and assigns.

20. All parties consent to the United States' and the State of Illinois' disclosure of this Agreement, and information about this Agreement, to the public.

21. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: ____

BY:

Laurie A. Oberembt
Civil Division
United States Department of Justice

DATED: ____

BY:

ERIC S. PRUITT
Assistant United States Attorney
United States Attorney's Office
Northern District of Illinois

DATED: ____

BY:

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

STATE OF ILLINOIS

DATED: ____

BY:

ROBERT BARBA
Assistant Attorney General
Office of the Illinois Attorney General

TEVA PHARMACEUTICALS USA, INC. and IVAX LLC

DATED: ____

BY: _____
DEBORAH GRIFFIN
Vice President, Finance
TEVA PHARMACEUTICALS USA, INC.

DATED: ____

BY: _____
MICHAEL MCHUGH
Vice President and General Manager
Teva Select Brands

DATED: ____

BY: _____
MARK FILIP
Kirkland & Ellis, LLP
Counsel for TEVA PHARMACEUTICALS USA, INC.